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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,570	11/08/2001	Jin Po-Lee	086748-20	7953

46725 7590 07/11/2007
BERND W. SANDT
900 DEERFIELD COURT
MIDLAND, MI 48640

EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

MAIL DATE	DELIVERY MODE
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07/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/019,570	Applicant(s) LEE, JIN PO	
	Examiner Lyle A. Alexander	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The claims presented in the 2/13/07 amendment are confusing. Page 1 of the amendment identifies claim "26.(New)" which is incorrect because claim 26 is pending in the application. The Office will assume this was a typographical error and examine the above claim as though it were – claim 35.(new)-- . Additionally, new claim 35 in paragraph "(b)" contains a typographical error "fro". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 35-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 "... said base and said cover forming the housing for said test strips extending beyond the housing ..." is not clear what structural elements are intended to accomplish this function. How can only a cover and a base form a housing ? How does this structurally differ from the previous claims that accomplish this same function ?

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 35-43 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Klimov et al.

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Klimov et al. teach an assay device comprising a plastic holder (102) for insertion of the test membranes (101). The holder (102) has plurality of slots for different test membranes (101). Each membrane (101) has a test zone (103) and a control site (104). Figures 1A-1B illustrate that each slot is defined by a floor, raised wall and open end to receive the sample. Column 10 lines 32-57 state each slot is sealed with cover panel (115) to prevent leakage. Column 10 lines 39-41 teach the sample contacts the membranes (101) via sample pads (109) through holes on the backside. Columns 5-6 lines 64-4 respectively teach a cup is employed to collect the sample from the top of the cup and interact with the holder (102) to facilitate transfer of sample to the membranes (101) [also see figure 1C]. Column 7 lines 7-12 teach the analytes of interest that include the claimed drugs of abuse. Result windows (113) and (114) are transparent. Seal(110) sits on top of sample pad(109) and seals it along its boarder.

The claimed base has been read on the taught holder (102), the claimed test strips on the taught membrane (10), the claimed cover on the taught cover panel (115), the claimed sample port on the taught sample pads (109) through holes on the back side and the claimed floor opposing the sample port on the taught cup. Seal(110) has been read on the removable cap enclosing the protruding ends,

Response to Arguments

Applicant's arguments filed 5/7/07 have been fully considered but they are not persuasive.

Applicant states figures 1A-B shows a device that does not employ a cover (see column 6 line 42 of Kimrov). The Office notes Kimrov teaches in column 6 line 42 the

absence of a "cover panel". The Office maintains figure 1A illustrate screw threads on the top of the device that are clearly intended to screw a cover on top of the device which is indistinguishable from the instant claims.

Applicant states holder(102) fails to teach the claimed multiple slots to hold multiple test strips. Kimrov teaches in figure 1A the holder supporting multiple test strips.

Applicant states the test strips taught by Kimrov do not meet the claimed limitations "... protruding ends of the test strip ... ". The Office the portion of the sample pad(109) protrudes from the end of the test strip and has been properly read on the instant claims.

Finally, Applicant states the 5/7/07 amendments have added language requiring accessing the sample through the seal. These remarks do not appear commensurate in scope with the pending claims that require the test strips to protrude from the housing that has been addressed above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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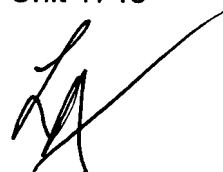
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander
Primary Examiner
Art Unit 1743

A handwritten signature in black ink, appearing to be 'Lyle A. Alexander', written over a horizontal line.